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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/573,973

02/22/2007

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P29617

9933

7055 7590 10/16/2009  
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EXAMINER

HENRY, MICHAEL C

ART UNIT

PAPER NUMBER

1623

NOTIFICATION DATE

DELIVERY MODE

10/16/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com  
pto@gbpatent.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/573,973	<b>Applicant(s)</b> SAKAMOTO ET AL.	
	<b>Examiner</b> MICHAEL C. HENRY	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-7, 9 and 10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-7, 9 and 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The amendment filed 02/04/09 affects the application, 10/573,973 as follows:

1. Claims 1-3, 5 and 6 have been amended. Claim 8 has been canceled. Applicant's amendments have overcome the rejections made under 35 U.S.C. 112, second paragraph and under 35 U.S.C. 102 and 103(a). Consequently, the said rejections are withdrawn. Upon further consideration, it was determined that indicated allowable subject matter of the prior office action, mailed 02/05/09 was not appropriate. Consequently, the said allowable subject matter is withdrawn. A new ground(s) rejection is set forth herein below.
2. The responsive to applicants' arguments is contained herein below.

Claims 1-3, 5-7, 9 and 10 are pending in application

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the phrase "wherein the stability of the vitamin is improved". However, the claim is indefinite since it is unclear how said vitamin is stabilized or what it is stabilized from or what constitutes a stabilization or an improved stability.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1623

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for improving the stability of specific vitamin such as calcium pantothenate (vitamin B5, VB5) from thermal decomposition and decomposition initiated by U.V. light in a cosmetic, a medicament, a foodstuff, and/or a feed by adding said compound to said cosmetic, a medicament, a foodstuff, and/or a feed, it does not reasonably provide enablement for stabilizing all vitamins in said composition by adding the compound of general formula (V) or a salt thereof to a cosmetic, a medicament, a foodstuff, and/or a feed .

For example, the stabilization of all or any one of the numerous vitamins which have completely different chemical structures, functional chemical groups and properties in general, would reasonably broadly encompass the stabilization of all those known and unknown vitamins as of the instant filing date, as well as those future known vitamins yet to be discovered or prepared which have completely different chemical structures, functional chemical groups and properties.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the

Art Unit: 1623

amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

1. The nature of the invention: The instant invention pertains to a method for stabilizing a vitamin contained in a cosmetic, a medicament, a foodstuff, and/or a feed from thermal decomposition and decomposition initiated by U.V. light by adding a compound represented by the general formula (V) or a salt thereof in claim 5 to the cosmetic, the medicament, the foodstuff, and/or the feed.

2. The state of the prior art: The skilled artisan would view the stabilization of all the numerous vitamins which have different chemical structures and properties by adding a specific compound to a cosmetic, a medicament, a foodstuff, and/or a feed, as not possible.

3. The predictability of the art, and the breadth of the claims:

It is highly unpredictable which vitamins or whether or not a particular vitamin can be stabilized by said compound and what particular ingredients or components must comprise the said cosmetic, a medicament, a foodstuff, and/or a feed in order for said stabilization to occur as required by the claim. Such determination would require numerous or several trials and experimental processes. Also, the amounts or quantity of the compound to be added and the amount or quantity and types of ingredients or components that comprises the said cosmetic, a medicament, a foodstuff, and/or a feed is unpredictable. That is, there is no routine, predictable way to prepare and stabilize all the numerous vitamins in each and every composition of vitamin/compound in a cosmetic, a medicament, a foodstuff, and/or a feed form. Thus, said preparation would require unpredictable experimentation. Furthermore, it should be noted that the claim requires that the said compound be able to stabilize all vitamins regardless of their

Art Unit: 1623

different structures, functions and functional groups and properties as a whole and consequently this is highly unpredictable.

4. The presence or absence of working examples: It is noted that the specification merely provides a working example to demonstrate improving the stability of the vitamin calcium pantothenate (vitamin B5, VB5) by dissolving adding a vitamin B6 derivative and calcium pantothenate (vitamin B5, VB5) in purified water (see page 38). That is, the evidence in the examples provided is not commensurate in scope with the claimed invention and does not demonstrate criticality of the numerous compounds that are encompassed by applicant's claimed method. See MPEP § 716.02(d).

Furthermore, it should be noted that the applicant states that "the inventors of the present invention also found that the aforementioned vitamin B6 derivative was stably maintained in a composition such as medicaments, foodstuffs, feeds, cosmetics and the like to exhibit superior effects, **and the derivative gave no influence on the stability of other vitamins in the composition**" (see page 3, 1<sup>st</sup> paragraph). Therefore, the skilled artisan has to exercise undue experimentation to practice the instant invention.

Thus, the specification fails to provide sufficient support of the method of broadly stabilizing all vitamins as encompassed by the instant claim. As a result, necessitating one of skill to perform an exhaustive search for the embodiments and method of preparations of said composition that are encompassed by the instant claims suitable to practice the claimed invention.

*Genentech*, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is

Art Unit: 1623

granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable”.

Therefore, in view of the Wands factor and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test compounds and compositions encompassed in the instant claims, with no assurance of success.

### ***Claim Rejections - 35 USC § 102***

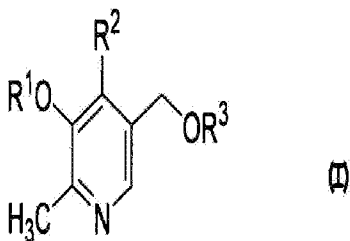
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Mineura et al. (Nippon Nogei Kagaku Kaishi (1972), 46(3), 111-18, Abstract Only).

Claim 1 is drawn to a compound represented by the following general formula (I) or a salt thereof:



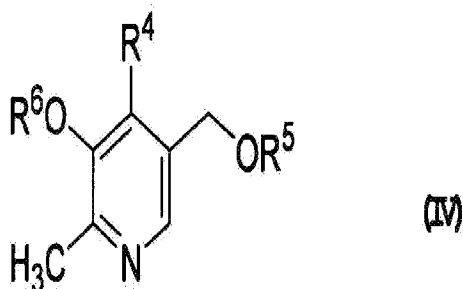
wherein R<sup>1</sup> represents a cyclic phosphate group bound to R<sup>2</sup>; R<sup>2</sup> represents -CH<sub>2</sub>OH, -CHO, -CH<sub>2</sub>NH<sub>2</sub>, -CH<sub>2</sub>-amino acid residue, or -CH<sub>2</sub>-OPO<sub>2</sub>H; and R<sup>3</sup> represents hydrogen atom, or -PO<sub>3</sub>H<sub>2</sub>. Mineura et al. disclose applicant's compound represented by the general formula (I)

Art Unit: 1623

wherein  $R^1$  represents a cyclic phosphate group bound to  $R^2$ ;  $R^2$  represents  $-\text{CH}_2\text{OH}$ ; and  $R^3$  represents hydrogen atom (see abstract). Mineura et al.'s compound has a Cas # of 36944-85-1 (see abstract). It should be noted that applicant's compound is also named 4H-1, 3, 2-Dioxaphosphorino[4,5-c]pyridine-5-methanol, 2-hydroxy-8-methyl-, 2-oxide (see abstract).

Claim 2 is drawn to the compound or a salt thereof according to claim 1, which is pyridoxine 3,4'-cyclic phosphate or a salt thereof. Mineura et al. disclose applicant's compound, pyridoxine 3,4'-cyclic phosphate (see abstract). Mineura et al.'s compound has a Cas # of 36944-85-1 (see abstract). It should be noted that applicant's compound is also named 4H-1, 3, 2-Dioxaphosphorino[4,5-c]pyridine-5-methanol, 2-hydroxy-8-methyl-, 2-oxide (see abstract).

Claim 3 is drawn to a compound represented by the following general formula (IV) or a salt thereof:



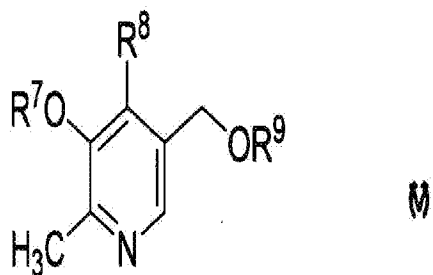
wherein  $R^4$  represents  $-\text{CH}_2\text{OH}$ ,  $-\text{CHO}$ , or  $-\text{CH}_2\text{NH}_2$ , or represents  $-\text{CH}_2\text{OH}$ ,  $-\text{CHO}$ , or  $-\text{CH}_2\text{NH}_2$  protected with a protective group;  $R^5$  represents hydrogen atom, a protective group of hydroxyl group, a phosphate group, or a protected phosphate group; and  $R^6$  represents a cyclic phosphate group bound to  $R^4$  which may have a protective group. Mineura et al. disclose applicant's compound represented by the general formula (IV) wherein  $R^6$  represents a cyclic phosphate group bound to  $R^4$ ;  $R^4$  represents  $-\text{CH}_2\text{OH}$ ; and  $R^5$  represents hydrogen atom (see



Art Unit: 1623

abstract). Mineura et al.'s compound has a Cas # of 36944-85-1 (see abstract). It should be noted that applicant's compound is also named 4H-1, 3, 2-Dioxaphosphorino[4,5-c]pyridine-5-methanol, 2-hydroxy-8-methyl-, 2-oxide (see abstract).

In claim 5, applicant claims a composition for a cosmetic, a medicament, a foodstuff, and/or a feed comprising a compound represented by the following general formula (V) or a salt thereof:



wherein R<sup>7</sup> represents a cyclic phosphate group bound to R<sup>8</sup>; R<sup>8</sup> represents -CH<sub>2</sub>OH, -CHO, -CH<sub>2</sub>NH<sub>2</sub>, -CH<sub>2</sub>-amino acid residue, or -CH<sub>2</sub>-OPO<sub>2</sub>H; and R<sup>9</sup> represents hydrogen atom, or -PO<sub>3</sub>H<sub>2</sub>. Mineura et al. disclose applicant's composition or compound represented by the general formula (V) wherein R<sup>7</sup> represents a cyclic phosphate group bound to R<sup>8</sup>; R<sup>8</sup> represents -CH<sub>2</sub>OH; and R<sup>9</sup> represents hydrogen atom (see abstract). Mineura et al.'s compound has a Cas # of 36944-85-1 (see abstract). It should be noted that applicant's compound is also named 4H-1, 3, 2-Dioxaphosphorino[4,5-c]pyridine-5-methanol, 2-hydroxy-8-methyl-, 2-oxide (see abstract). It should be noted that it is well settled that "intended use" of a composition or product, e.g., for a cosmetic or a medicament, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

***Claim Rejections - 35 USC § 103***

Art Unit: 1623

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mineura et al. (Nippon Nogei Kagaku Kaishi (1972), 46(3), 111-18, Abstract Only).

In claim 7, applicant claims a composition for a cosmetic, a medicament, foodstuff, and/or a feed containing a compound represented by the general formula (V) or a salt thereof mentioned in claim 5 and at least one kind of vitamin, wherein stability of the vitamin is improved.

Mineura et al. disclose applicant's composition or compound represented by the general formula (V) wherein  $R^7$  represents a cyclic phosphate group bound to  $R^8$ ;  $R^8$  represents  $-CH_2OH$ ; and  $R^9$  represents hydrogen atom (see abstract). Mineura et al.'s compound has a Cas # of 36944-85-1 (see abstract). It should be noted that applicant's compound is also named 4H-1, 3, 2-Dioxaphosphorino[4,5-c]pyridine-5-methanol, 2-hydroxy-8-methyl-, 2-oxide (see abstract). Also, it is known in the art that Mineura et al.'s compound can be utilized as vitamin B6 (pyridoxine).

The difference between applicants claimed composition and the composition of Mineura et al. is that applicant's composition also contains another vitamin.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, to prepare a composition comprising a combination of Mineura et al.'s

Art Unit: 1623

compound and another vitamin which have the same utility in order to use it in nutritive, food stuff or a medicament.

One having ordinary skill in the art would have been motivated, to prepare a composition comprising a combination of Mineura et al.'s compound and another vitamin which have the same utility in order to use it in a nutritive, a food stuff or a medicament. It should be noted that it is obvious to determine the properties of the prepared composition or the components of the composition such as the stability of the components of the composition.

Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Savini Emile Constantin (FR 2349330 A) in view of Mineura et al.(Nippon Nogei Kagaku Kaishi (1972), 46(3), 111-18, Abstract Only).

Claim 9 is drawn to a composition comprising (A) a compound represented by the general formula (V) according to claim 5, and (B) one or more kinds of substances selected from the group consisting of a whitening agent, an antioxidant, an antiphlogistic, a circulation accelerator, a cell activation agent, and an ultraviolet absorber, which is used as a whitening agent, an anti-aging agent, and/or an agent for suppressing wrinkle formation by exposure to ultraviolet light. Claim 10 is drawn to a whitening agent containing (A) a compound represented by the general formula (V) mentioned in claim 5, and (B) arbutin.

Savini Emile Constantin discloses that compositions comprising a pyridoxine and an antioxidant which can be used to treat hyperlipidaemia (see abstract).

The difference between applicants claimed composition and the composition of Savini Emile Constantin is the specific pyridoxine compound used.

Art Unit: 1623

Mineura et al. disclose a compound represented by the general formula (V) wherein R<sup>7</sup> represents a cyclic phosphate group bound to R<sup>8</sup>; R<sup>8</sup> represents -CH<sub>2</sub>OH; and R<sup>9</sup> represents hydrogen atom (see abstract). Mineura et al.'s compound has a Cas # of 36944-85-1 (see abstract). It should be noted that applicant's compound is also named 4H-1, 3, 2-Dioxaphosphorino[4,5-c]pyridine-5-methanol, 2-hydroxy-8-methyl-, 2-oxide (see abstract). Also, it is known in the art that Mineura et al.'s compound can be utilized as vitamin B6 (pyridoxine).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, to prepare a composition comprising a combination of a pyridoxine such as Mineura et al.'s pyridoxine compound and an antioxidant to treat hyperlipidaemia, since Savini Emile Constantin discloses that a pyridoxine and an antioxidant can be used.

One having ordinary skill in the art would have been motivated, to prepare a composition comprising a combination of a pyridoxine such as Mineura et al.'s pyridoxine compound and an antioxidant to treat hyperlipidaemia, since Savini Emile Constantin discloses that a pyridoxine and an antioxidant can be used. It should be noted that claim 10 is also encompassed by this rejection since it is obvious to use an antioxidant such as arbutin, since Savini Emile Constantin disclose that a pyridoxine and an antioxidant can be used. Also, it should be noted that it is well settled that "intended use" of a composition or product, e.g., for a whitening agent, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

### ***Response to Arguments***

Art Unit: 1623

Applicant's arguments with respect to claims 1-3, 5-7, 9 and 10 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry  
October 12, 2009.

/Shaojia Anna Jiang/  
Supervisory Patent Examiner  
Art Unit 1623